510(k) Summary

AUG 2 8 2009

Applicant:

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Date of preparation of 510(k) summary:

June 12, 2009

Device Name:

Trade name – ELVIS®HSV ID and D³ Typing Test System
Common name – HSV Culture and Typing
Classification name – Antisera, fluorescent, herpesvirus hominis 1,2
Product Code – GQL
Regulation – 21 CFR Sec. 866.3305 Herpes simplex virus serological assays;
Panel – Microbiology (83)

Legally marketed devices to which equivalence is claimed:

ELVIS®HSV ID/Typing Test System **(k971662)**

Intended Use:

The ELVIS®HSV ID and D3 Typing Test System provides Cells, Replacement Medium and Test Reagents for the culture, qualitative identification and typing of Herpes simplex virus (HSV) from cutaneous or mucocutaneous specimens collected from patients with clinical suspicion of HSV infection. The performance characteristics of this assay have not been established for antiviral therapy, prenatal monitoring or CSF specimens.

Device Description:

The ELVIS®HSV ID and D3 Typing Test System provides Cells, Replacement Medium and Test Reagents for the culture, qualitative identification and typing of herpes simplex virus (HSV) from cutaneous or mucocutaneous specimens as an aid in the diagnosis of HSV type 1 (HSV-1) and HSV type 2 (HSV-2) infections. The performance characteristics of this assay have not been established for antiviral therapy, prenatal monitoring or use with cerebral spinal fluid specimens.

ELVIS®HSV Cells are genetically engineered Baby Hamster Kidney (BHK) cells, which, when infected with either HSV-1 or HSV-2, are induced to generate and accumulate an endogenous, intracellular bacterial enzyme, β-galactosidase. Other related viruses (e.g., *Varicella zoster*) are not capable of inducing the formation of this enzyme. HSV infection of the ELVIS®HSV Cells also results in the formation of HSV-type-specific proteins. The presence of these proteins can be detected microscopically when fluorescent labeled HSV-type-specific antibodies are used. The two Type 1 monoclonal antibodies used in ELVIS® are directed against specific to epitopes on the HSV-1 protein. The three Type 2 monoclonal antibodies are directed against the HSV-2 glycoproteins C, G and a recombinant glycoprotein G that occur in the cytoplasm of infected cells.

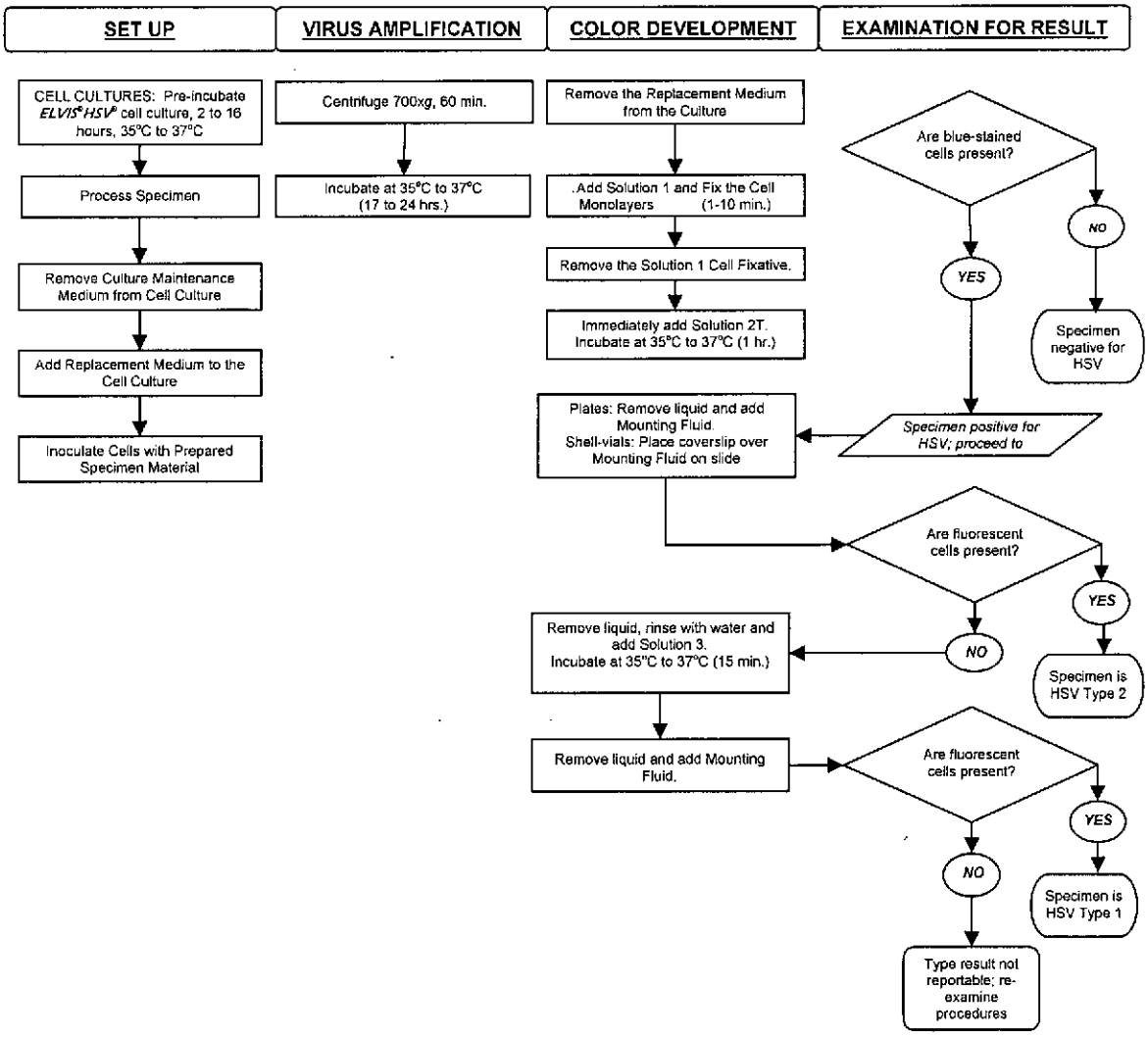
The ELVIS®HSV ID and D^3 Typing Test System consists of:

1. ELVIS®HSV Cells: The ELVIS®HSV Cells have a routine use period of 7 days from customer receipt while all other components have a shelf-life of months (see expiration date on label of each component). ELVIS®HSV Cells are provided as 75% to 95% confluent monolayers in shell-vials with or without coverslips, or in multi-well plates with or without coverslips, and up to 24 monolayers per plate. Each monolayer is covered by at least 0.75-mL of Eagle's Minimum Essential Medium (EMEM) with fetal bovine serum (FBS), penicillin, and streptomycin. Cells are characterized by isoenzyme analysis and have been tested and found free of Mycoplasma spp. and other adventitious organisms.
2. ELVIS®HSV Replacement Medium: Sterile EMEM containing FBS, Penicillin, Streptomycin and Amphotericin B. ELVIS®HSV Replacement Medium is for use with ELVIS®HSV Shell-Vials and Multi-well Plates.
3. ELVIS® HSV Solution 1 (Cell Fixative): an aqueous acetone solution.
4. ELVIS®HSV Solution 2T (Staining Buffer): A diluted solution of X-Gal (5-Bromo-4-Chloro-3-Indolyl-β-D-Galactopyranoside), N,N-Dimethylformamide, iron, sodium and magnesium salts, fluorescein-labeled HSV-2-specific murine MAbs (directed against

HSV-2 glycoproteins C, G, and a recombinant glycoprotein G) and non-labeled HSV-1-specific murine MAbs (specific to epitopes on the HSV-1 protein UL42), penicillin, streptomycin, bovine serum albumin and Evans Blue in an aqueous, buffered solution.

5. ELVIS®HSV Solution 3: An aqueous, stabilized, buffered solution containing fluorescein-labeled, affinity purified goat-anti-mouse IgG antibody and Evans Blue with sodium azide as preservative.
6. ELVIS®HSV Mounting Fluid (Buffered Glycerol): Aqueous, stabilized, buffered glycerol (pH 7.3 +/- 0.5), containing sodium azide as preservative.
7. 40X PBS Concentrate. 25-mL: One bottle of a 40X PBS concentrate consisting of 0.4% sodium azide (0.1% sodium azide after dilution to 1X using de-mineralized water).

Flowchart of ELVIS® Procedure



Intended Use:

The ELVIS®HSV ID and D3 Typing Test System provides Cells, Replacement Medium and Test Reagents for the culture, qualitative identification and typing of herpes simplex virus (HSV) from cutaneous or mucocutaneous specimens as an aid in the diagnosis of HSV type 1 (HSV-1) and HSV type 2 (HSV-2) infections. The performance characteristics of this assay have not been established for antiviral therapy, prenatal monitoring or use with cerebral spinal fluid specimens.

Technological Characteristics, Compared to Predicate Device:

Table 5.1: Subject Device and Predicate Device Characteristics		
Similarities		
Item	**Subject Device**	**Predicate Device**
Intended Use	The *ELVIS®HSV* ID and D³ Typing Test System provides Cells, Replacement Medium and Test Reagents for the culture, qualitative identification and typing of *Herpes simplex* virus (HSV).	Same
Assay Format	Shell-vials or Multi-well plates	Same
Assay principle	Genetically engineered Baby Hamster Kidney (BHK) cells, which, when infected with either HSV-1 or HSV-2, are induced to generate and accumulate an endogenous, intracellular bacterial enzyme, β-galactosidase.	Same
Labeling Method	Direct Method – Using fluorescein isothiocyanate (FITC) to label HSV-2 Specific monoclonal antibodies, and goat-anti-mouse IgG antibody	Same
Differences		
Item	**Subject Device**	**Predicate Device**
Monoclonal Antibodies (MAbs)	HSV-1: non-labeled specific to epitopes on the HSV-1 protein UL42 HSV-2: FITC labeled specific	HSV-1: non-labeled specific to HSV-1 viral protein occurring in the nuclei of infected cells and an HSV-1 glycoprotein C HSV-2: FITC labeled specific for

Table 5.1: Subject Device and Predicate Device Characteristics		
	for HSV-2 glycoproteins C, G, and a recombinant glycoprotein G	HSV-2 glycoproteins C, and G

Performance Testing – Non-Clinical

A. Analytical Sensitivity

Analytical detection limits for HSV-1 and HSV-2 were addressed with results reported in numbers of blue staining cells per cell monolayer. Each master stock (~1e7-$TCID_{50}$ per mL) virus preparation underwent a series of ten-fold dilutions, which were subsequently inoculated into a 96-well ELVIS®HSV cell culture plate. The plates were centrifuged at 700xg for 60 minutes, and then incubated at 35°C to 37°C for 17-hours. Each well was stained with the subject and predicate devices then examined at 200X magnification and the number of blue staining cells counted. Table 5.2. below lists the results for each virus strain tested.

Table 5.2: Limit of Detection compared between ELVIS Subject (D^3 ELVIS) and Predicate (Current ELVIS Kit Formulation) Typing Systems

Virus strain	Virus per Inoculum	Blue staining cells/well	
		ELVIS Predicate	ELVIS Subject
HSV-1 Strain F ATCC VR-733	65-$TCID_{50}$	74, 67, 65, 69, 70, 64	76, 70, 63, 68, 72, 71
	6.5-$TCID_{50}$	9, 8, 11, 7, 7, 12	10, 9, 9, 11, 7, 13
	0.65-$TCID_{50}$	1, 2, 1, 1, 3, 3	3, 2, 4, 3, 1, 1
	0.065-$TCID_{50}$	0, 0, 3, 1, 1, 0	0, 0, 1, 2, 0, 0
	0.0065-$TCID_{50}$	0, 0, 0, 0, 0, 0	0, 0, 0, 0, 0, 0
HSV-1 CW0H0062 Clinical Isolate Passage 2	85-$TCID_{50}$	70, 79, 75, 72, 80, 67	82, 77, 72, 65, 76, 85
	8.5-$TCID_{50}$	10, 7, 7, 6, 9, 6	11, 10, 8, 6, 7, 7
	0.85-$TCID_{50}$	0, 1, 3, 0, 0, 1, 0	2, 0, 0, 0, 2, 2
	0.085-$TCID_{50}$	0, 0, 0, 0, 1, 0	1, 0, 0, 0, 1, 0
	0.0085-$TCID_{50}$	0, 0, 0, 0, 0, 0	0, 0, 0, 0, 0, 0
HSV-1 CWOH0085 Clinical Isolate Passage 2	60-$TCID_{50}$	39, 47, 52, 41, 42, 48	46, 48, 37, 42, 47, 50
	6.0-$TCID_{50}$	6, 10, 11, 8, 7, 15	7, 14, 9, 8 ,11, 7
	0.6-$TCID_{50}$	2, 0, 2, 0, 0, 1	1, 1, 0, 0, 0, 1
	0.06-$TCID_{50}$	0, 0, 0, 0, 0, 0	0, 0, 0, 0, 0, 0
HSV-2 G Strain ATCC VR-734	100-$TCID_{50}$	92, 102, 95, 91, 97, 90	95, 96, 97, 98, 89, 103
	10-$TCID_{50}$	12, 11, 17, 9, 9, 10	12, 12, 7, 16, 13, 12
	1.0-$TCID_{50}$	3, 2, 1, 1, 3, 4	5, 1, 2, 2, 1, 3
	0.1-$TCID_{50}$	0, 1, 0, 1, 0, 0	1, 0, 0, 0, 1, 1
	0.01-$TCID_{50}$	0, 0, 0, 0, 0, 0	0, 0, 0, 0, 0, 0

Table 5.2: Limit of Detection compared between ELVIS Subject (D^3 ELVIS) and Predicate (Current ELVIS Kit Formulation) Typing Systems			
HSV-2 CWOH0082 Clinical Isolate Passage 2	80-$TCID_{50}$	70, 67, 73, 78, 70, 62	76, 77, 64, 80, 70, 69
	8.0-$TCID_{50}$	8, 7, 10, 11, 6, 5	7, 8, 14, 11, 11, 9
	0.8-$TCID_{50}$	1, 0, 3, 3, 2, 2, 1	2, 1, 1, 3, 1, 0
	0.08-$TCID_{50}$	0, 0, 1, 0, 0, 0	0, 1, 0, 0, 0, 0
	0.008-$TCID_{50}$	0, 0, 0, 0, 0, 0	0, 0, 0, 0, 0, 0
HSV-2 CWOH0091 Clinical Isolate Passage 2	55-$TCID_{50}$	53, 61, 55, 62, 67, 65	70, 62, 55, 57, 53, 59
	5.5-$TCID_{50}$	3, 7, 7, 9, 2, 4	4, 4, 7, 8, 10, 3
	0.55-$TCID_{50}$	1, 0, 0, 2, 2, 1	3, 1, 0, 0, 2, 2
	0.055-$TCID_{50}$	0, 0, 0, 1, 0, 0	1, 0, 0, 0, 0, 0
	0.0055-$TCID_{50}$	0, 0, 0, 0, 0, 0	0, 0, 0, 0, 0, 0

In this study, the detection limit for the test is defined as the lowest inoculum level at which positive wells (i.e., containing blue staining cells) are observed, in terms of $TCID_{50}$. The results presented in Table 5.2 above indicate that detection limit for both subject and predicate devices averages between 0.65- and 8.5-$TCID_{50}$ for HSV-1 and 0.1 and 8.0-$TCID_{50}$ for HSV-2 depending on the strain.

B. Cross Reactivity

The specificity of the MAbs used in the device was assessed using the organisms listed in Table 5.3. The subject device *Solution 2T* at 2X concentration was tested in duplicate on the prepared slides. After 1-hour at 37°C, the slides were rinsed with PBS and the subject device *Solution 3* secondary stain was added and incubated at 37°C for 15 minutes. After rinsing and applying *Mounting Fluid*, the slides were examined at 400X using a fluorescence microscope.

Table 5.3: Respiratory Cross-Reactivity Testing			
Organism	Strain or Type	ELVIS HSV Typing Reagent at 2X concentration [Positive (+) or Negative (-) for Reactivity]	Concentrations of targets (viruses: $TCID_{50}$ inoculum level; bacteria: CFU)
Viruses			
Adenovirus	Type 1	-	1000-$TCID_{50}$
	Type 3	-	1000-$TCID_{50}$
	Type 5	-	1000-$TCID_{50}$
	Type 6	-	1000-$TCID_{50}$
	Type 7	-	1000-$TCID_{50}$

	Type 8	-	1000-$TCID_{50}$
	Type 10	-	1000-$TCID_{50}$
	Type 13	-	1000-$TCID_{50}$
	Type 14	-	1000-$TCID_{50}$
	Type 18	-	1000-$TCID_{50}$
	Type 31	-	1000-$TCID_{50}$
Influenza A	Aichi (H3N2)	-	1000-$TCID_{50}$
	Mal (H1N1)	-	1000-$TCID_{50}$
	Hong Kong (H3N2)	-	1000-$TCID_{50}$
	Denver (H1N1)	-	1000-$TCID_{50}$
	Port Chalmers (H3N2)	-	1000-$TCID_{50}$
	Victoria (H3N2)	-	1000-$TCID_{50}$
	New Jersey (HSWN1)	-	1000-$TCID_{50}$
	WS (H1N1)	-	1000-$TCID_{50}$
	PR (H1N1)	-	1000-$TCID_{50}$
Influenza B	Hong Kong	-	1000-$TCID_{50}$
	Maryland	-	1000-$TCID_{50}$
	Mass	-	1000-$TCID_{50}$
	GL	-	1000-$TCID_{50}$
	Taiwan	-	1000-$TCID_{50}$
	JH-001 Isolate	-	1000-$TCID_{50}$
	Russia	-	1000-$TCID_{50}$
RSV	Long	-	1000-$TCID_{50}$
	Wash	-	1000-$TCID_{50}$
	9320	-	1000-$TCID_{50}$
Parainfluenza 1	C-35	-	1000-$TCID_{50}$
Parainfluenza 2	Greer	-	1000-$TCID_{50}$
Parainfluenza 3	C-243	-	1000-$TCID_{50}$
Parainfluenza 4	M-25	-	1000-$TCID_{50}$
Parainfluenza 4b	CH-19503	-	1000-$TCID_{50}$
CMV	AD169	-	Control Slide
Varicella-zoster	Webster	-	Control Slide
Echovirus 7	ODH-594684	-	Control Slide
Coxsackievirus A9	ODH-36685	-	Control Slide
Coxsackievirus B2	ODH-185	-	Control Slide
Enterovirus 71	ODH 02-89	-	Control Slide
Bacteria*			

Acinetobacter calcoaceticus		-	$3.6x10^9$ CFU
Bordetella bronchiseptica		-	$1.1x10^{10}$ CFU
Bordetella pertussis		-	$4.3x10^9$ CFU
Chlamydia trachomatis	LGV-II	-	Control Slide
Corynebacterium diphtheriae		-	$5.7x10^7$ CFU
Escherichia coli		-	$7.5x10^8$ CFU
Haemophilis influenzae type A		-	$4.1x10^9$ CFU
Klebsiella pneumoniae		-	$1.2x10^9$ CFU
Moraxella cartarrhalis		-	$1.2x10^{10}$ CFU
Mycoplasma hominis		-	$3.5x10^{10}$ CFU
Mycoplasma orale		-	$6.6x10^9$ CFU
Mycoplasma pneumoniae		-	$7.9x10^9$ CFU
Mycoplasma salivarium		-	$7.7x10^8$ CFU
Proteus mirabilis		-	$3.6x10^9$ CFU
Pseudomonas aeruginosa		-	$1.0x10^8$ CFU
Salmonella enteriditis		-	$8.7x10^9$ CFU
Salmonella typhimurium		-	$7.5x10^9$ CFU
Staphylococcus aureus		+†	$6.3x10^9$ CFU
Streptococcus agalactiae		-	$5.5x10^8$ CFU
Streptococcus pneumoniae		-	$6.7x10^9$ CFU
Streptococcus pyogenes		-	$6.9x10^9$ CFU
Yeast*			
Candida glabrata		-	$1.6x10^6$ CFU

* Turbidity or a color change to yellow indicates possible bacterial contamination and may render a test result unreliable, due either to a technical contamination during the culture setup or to a contaminated specimen. We recommend the original specimen be filtered and re-cultured.

† Light background fluorescent staining may occur with specimens contaminated with *Staphylococcus aureus* strains containing large amounts of protein A. Protein A binds to the Fc portions of the conjugated antibodies. Such binding can be distinguished from viral antigen binding on the basis of morphology, e.g., *S. aureus*-bound fluorescence appears as small (~1 micron diameter), bright dots.

C. Reproducibility Testing

The reproducibility of the device was assessed by creating ten panels of proficiency-level frozen virus suspensions. The panels were processed at each testing site. Each panel was inoculated and stained once according to the ELVIS®HSV ID and D³ Typing Test System instructions for use. Two panels per day were tested on separate plates for 5-days (10 total runs).

Panel members were manufactured by diluting high-titered master stocks. The dilutions were made with the same lot of EMEM with 10% Fetal Bovine Serum used as the negative control. These dilutions were frozen at -70°C and sent to the testing labs. The dilution's titer was confirmed pre- and post freezing and found to fall within the expected infectivity range for the study: low level should exhibit less than 10% of the cells showing fluorescence; high level should exhibit greater than 10% but less than 50% of the cells showing fluorescence.

Table 5.4: Panel Member Discriptions

Panel Member	Description
HSV-1 low level	SF029* lab adapted QC strain; 200 $TCID_{50}$/mL
HSV-1 high level	SF029 lab adapted QC strain; 1000 $TCID_{50}$/mL
HSV-2 low level	SF028† lab adapted QC strain; 200 $TCID_{50}$/mL
HSV-2 high level	SF028 lab adapted QC strain; 1000 $TCID_{50}$/mL
Negative	EMEM with 10% Fetal Bovine Serum

*Isolate confirmed as HSV-1 by 2 FDA cleared IVD devices
†Isolate confirmed as HSV-2 by 2 FDA cleared IVD devices

Table 5.5 presents the daily results from each panel member at each site.

Table 5.5: Daily Results

Panel Member		Day 1		Day 2		Day 3		Day 4		Day 5	
		Run 1	Run 2	Run 1	Run 2	Run 1	Run 2	Run 1	Run 2	Run 1	Run 2
HSV-1 low level	Site 1	+/-	+/-	+/-	+/-	1+	+/-	+/-	1+	1+	+/-
	Site 2	+/-	1+	1+	1+	+/-	1+	1+	1+	+/-	1+
	Site 3	1+	1+	1+	1+	1+	1+	1+	1+	+/-	1+
HSV-1 high level	Site 1	1+	1+	1+	1+	1 to 2+	1+	1+	1+	1+	1+
	Site 2	1+	1+	1+	2+	1+	1+	3+	2+	1+	2+
	Site 3	2+	2+	2+	2+	2+	2+	2+	3+	1+	2+
HSV-2 low level	Site 1	1+	+/-	1+	+/-	1+	+/-	+/-	+/-	1+	+/-
	Site 2	+/-	1+	1+	1+	1+	1+	2+	1 to 2+	1+	2+
	Site 3	1+	1+	1+	1+	1+	1+	1+	1+	+/-	1+
HSV-2 high level	Site 1	1+	+/-	1+	+/-	1+	1+	1+	1+	1+	1+
	Site 2	2+	2+	2+	2+	2+	1+	3+	3+	3+	2+
	Site 3	2+	3+	3+	3+	2+	3+	2+	3+	1+	2+
Negative	Site 1	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
	Site 2	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

	Site 3	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

The presence of HSV was reported in 100% (120/120) of the wells in which infected cells were present and the expected type was reported 100% (60/60) for HSV-1 and 100% (60/60) for HSV-2. The absence of HSV was reported in 100% (30/30) of the vials in which no virus was present. Controls performed as expected during each run.

Table 5.6: Reproducibility Study Summary Results

	Panel Member	HSV-1 SF029 Low Level	HSV-1 SF029 Mid Level	HSV-2 SF028 Low Level	HSV-2 SF028 Mid Level	Negative Control	Total % Agreement
	Concentration	200 $TCID_{50}$/mL	1000 $TCID_{50}$/mL	200 $TCID_{50}$/mL	1000 $TCID_{50}$/mL	Non-infected cells	
Site 1	Agreement with Expected result	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	**50/50 (100%)**
Site 2	Agreement with Expected result	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	**50/50 (100%)**
Site 3	Agreement with Expected result	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	**50/50 (100%)**
	Total Agreement with Expected result	30/30 (100%)	30/30 (100%)	30/30 (100%)	30/30 (100%)	30/30 (100%)	**150/150 (100%)**
	95% CI	88.4%-100%	88.4%-100%	88.4%-100%	88.4%-100%	88.4%-100%	**97.6%-100%**

Performance Testing – Clinical

Studies were performed at three locations using 735 specimens submitted, April through May, 2009, for HSV culture. The number of specimens cultured at each of the three sites: Study site 1 - 299 specimens; Study site 2 - 136 specimens; and Study site 3 - 300 specimens. The specimens were cultured in duplicate and stained concurrently with both devices. The data generated by each site was similar and has been combined for presentation. Of these 735 specimens, 16 were excluded from the final analysis for the reasons listed in Table 5.7.

Table 5.7: Combined Study Sites Rejected Specimens/Samples

Exclusion criteria – Toxic to cell culture	13
Exclusion criteria - Contaminated	3
Grand Total	16

Table 5.8 shows the age and gender distribution for individuals included in the Study:

Table 5.8: Combined Study Sites - Age and Gender Distribution (720 Specimens)

Age Range	Values are # Positive (based on Subject Device) / Total		
	Male	Female	Total
0 to 1 month	0/9	1/9	1/18
>1 month to 2 years	0/1	0/1	0/2
>2 to 12 years	1/7	4/7	5/14
>12 to 21 years	4/22	54/110	58/132
22 to 30 years	9/34	71/146	80/180
31 to 40 years	10/37	44/121	54/158
41 to 50 years	8/22	18/64	26/86
51 to 60 years	3/14	15/50	18/64
>60 years	3/18	9/47	12/65
Unknown age	0/0	0/0	0/0
Grand Total	38/165	216/555	254/719

Table 5.9 shows the specimen source distribution for the Study:

Table 5.9: Combined Study Sites - Specimen Source Distribution (719 Specimens) Values are # Positive (based on Subject Device) / Total

Source	Total Specimens	Unknown +/-	Genital +/-	Penis +/-	Vaginal +/-	Labia +/-	Cervical +/-	Wound +/-	Perineum * +/-	Vulva +/-	Urethra +/-	Lesion +/-	Face‡‡ +/-	Mouth ** +/-	Skin ‡ +/-	Bartholin Cyst +/-
	254/ 719	66/ 175	18/ 50	14/ 44	45/ 105	23/ 47	18/ 50	0/4	16/ 40	23/ 66	0/ 12	5/ 14	4/ 32	9/ 37	13/ 42	1/1

* Perineum: anal, groin, buttock, perianal, tailbone
** Mouth: mouth, lip, throat, NP Wash, Tongue
‡ Skin: skin, arm, back, breast, finger, foot, leg, thigh, breast, abdomen, hand
‡‡ Face: cheek, chin, eye, nasal

Table 5.10 shows the comparison of the Subject device with the Predicate device for the isolation and detection of HSV at Study Sites Combined:

Table 5.10: Combined Study Sites - Subject Device compared to Predicate Device for the Isolation of HSV			
Specimen (719 specimens)		**Predicate Device** (Current ELVIS Kit Formulation)	
		Pos	Neg
Subject Device (D^3 ELVIS)	Pos	250	5
	Neg	1	463
Positive Percent Agreement (PPA)		99.6% (250/251)	
95% CI-PPA		97.8 – 100%	
Negative Percent Agreement (NPA)			98.9% (463/468)
95% CI-NPA			97.5 – 99.7%

Table 5.11 shows the comparison of the Subject device with the Predicate device for the identification of HSV-2 at Study Sites Combined:

Table 5.11: Combined Study Sites - Subject Device compared to Predicate Device for the Typing of HSV-2			
Specimen (106 specimens)		**Predicate Device** HSV-2 (Current ELVIS Kit Formulation)	
		Pos	Neg
Subject Device HSV-2 (D^3 ELVIS)	Pos	145	6
	Neg	1	98
Positive Percent Agreement (PPA)		99.3% (145/146)	
95% CI-PPA		96.2 – 100%	
Negative Percent Agreement (NPA)			94.2% (98/104)
95% CI-NPA			87.9 – 97.9%

Table 5.12 shows the comparison of the Subject device with the Predicate device for the identification of HSV-2 at Study Sites Combined:

Table 5.12: Combined Study Sites - Subject Device compared to Predicate Device for the Typing of HSV-1			
Specimen (36 specimens)		**Predicate Device** HSV-1 (Current ELVIS Kit Formulation)	
		Pos	Neg
Subject Device HSV-1 (D^3 ELVIS)	Pos	90	1
	Neg	0	7
Positive Percent Agreement (PPA)		100% (32/32)	

95% CI-PPA	96.0 – 100%	
Negative Percent Agreement (NPA)		87.5% (7/8)
95% CI-NPA		47.3 – 99.7%

The analytical testing and study results from the combined sites demonstrate that the ELVIS®HSV ID and D^3 Typing Test System results when compared to the results obtained with the FDA-cleared ELVIS®HSV ID/Typing Test System demonstrated adequate performance to be considered substantially equivalent for the qualitative isolation and identification of HSV-1 and HSV-2 in ELVIS®HSV cell cultures.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

AUG 2 8 2009

Ronald H. Lollar
Diagnostic Hybrids, Inc.
1055 East State Street Suite 100
Athens, Ohio 45701

Re: K091753
Trade/Device Name: ELVIS HSV ID and D^3 Typing Test System
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes simplex virus serological assays
Regulatory Class: Class II
Product Code: GQL
Dated: June 12, 2009
Received: June 16, 2009

Dear Mr. Lollar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

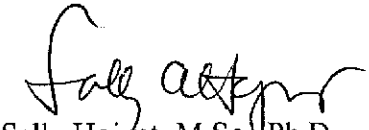
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k091753

Device Name: **ELVIS® HSV ID and D^3 Typing Test System**

Indications For Use:

The ELVIS®HSV ID and D3 Typing Test System provides Cells, Replacement Medium and Test Reagents for the culture, qualitative identification and typing of herpes simplex virus (HSV) from cutaneous or mucocutaneous specimens as an aid in the diagnosis of HSV type 1 (HSV-1) and HSV type 2 (HSV-2) infections. The performance characteristics of this assay have not been established for antiviral therapy, prenatal monitoring or use with cerebral spinal fluid specimens.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 091753